

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF PENNSYLVANIA**

<b>JOHN BARTOLI,</b>	:	
	:	
<b>Plaintiff</b>	:	<b>CIVIL ACTION NO. 3:13-0724</b>
	:	
<b>v.</b>	:	<b>(JUDGE MANNION)</b>
	:	
<b>NOVARTIS PHARMACEUTICALS CORPORATION,</b>	:	
	:	
<b>Defendant</b>	:	

**M E M O R A N D U M**

Pending before the court is defendant Novartis Pharmaceuticals Corporation's ("NPC") motion to exclude the specific causation testimony of plaintiff's non-retained experts Drs. Patrick Adonizio, Timothy Atkinson, James Specter, Samuel A. Falcone, James R. Bruno, Witold B. Rybka, Mary Lou Decker, and Arthur Meyer, and of retained experts Drs. Robert Marx and Diane Stern. (Doc. [159](#)). The motion is **DISMISSED IN PART, GRANTED IN PART, AND DENIED IN PART.**

Throughout the country, cancer patients who have been treated with two of NPC's drugs, and who have afterwards developed osteonecrosis of the jaw, a debilitating and painful disease in which the jaw bone becomes exposed, have sued in product liability actions. Plaintiff John Bartoli is one of these patients. NPC is challenging the ability of Mr. Bartoli's treating physicians and medical experts to opine about whether his ONJ was caused

by NPC's drugs.

## **I. BACKGROUND**

Aredia<sup>®</sup> and Zometa<sup>®</sup> are two FDA-approved drugs, called intravenous bisphosphonates ("BP"), manufactured by Novartis. The drugs are administered for treatment of advanced cancers which affect the bones. Plaintiff John Bartoli was treated with Aredia<sup>®</sup> and Zometa<sup>®</sup> for multiple myeloma.<sup>1</sup> He alleges that as a result of using the BP drugs, he developed osteonecrosis<sup>2</sup> of the jaw (ONJ).

This case is a pharmaceutical products liability action in which the plaintiff brings claims for strict products liability, negligence, and breach of warranty. (Doc. [1](#)). The case was transferred here from the Eastern District of New York on March 19, 2013. (Doc. [58](#)). Before the transfer, the case was

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<sup>1</sup>Multiple myeloma is a cancer formed by malignant plasma cells. Normal plasma cells are found in the bone marrow and are an important part of the immune system. When plasma cells become cancerous and grow out of control, they can produce a tumor called a plasmacytoma. These tumors generally develop in a bone, but they are also rarely found in other tissues. When there is more than one plasma cell tumor, it is called multiple myeloma. <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma>.

<sup>2</sup>Osteonecrosis, which is also called avascular necrosis or aseptic necrosis, is the death of bone cells due to decreased blood flow. It can lead to pain and collapse of areas of bone. [http://www.rheumatology.org/Practice/Clinical/Patients/Diseases\\_And\\_Conditions/Osteonecrosis/](http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Osteonecrosis/).

part of the Aredia<sup>®</sup> and Zometa<sup>®</sup> products liability multi-district litigation (“MDL”) in the Middle District of Tennessee for pre-trial purposes. (MDL No. 1760). The instant motion was filed with the MDL before the case was transferred to this court, but was not ruled on.

## II. LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which requires an expert witness to have "specialized knowledge" regarding the area of testimony. The Third Circuit has explained, "The basis of this specialized knowledge can be practical experience as well as academic training and credentials," and "[w]e have interpreted the specialized knowledge requirement liberally." [Betterbox Commc'ns Ltd. v. BB Techs., Inc.](#), 300 F.3d 325, 327-28 (3d Cir. 2002) (internal citations omitted). The Federal Rules of Evidence embody a strong preference for admitting any evidence that may assist the trier of fact. *Id.* Moreover, Rule 702 "has a liberal policy of admissibility." [Kannankeril v. Terminix Int'l, Inc.](#), 128 F.3d 802, 806 (3d Cir.1997).

When faced with a proffer of expert testimony, the court must determine "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." [Daubert](#), 509 U.S., at 592. The Daubert court held that the Federal Rules of Evidence “assign to the trial judge the task of ensuring that an expert's testimony both

rests on a reliable foundation and is relevant to the task at hand." *Id.*, at 597. The test of reliability is "flexible," and Daubert's list of specific factors - testing, peer review, error rates, and "acceptability" in the relevant scientific community - neither necessarily nor exclusively applies to all experts or in every case. [Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141 \(1999\)](#).

In performing its gatekeeping function to determine whether an expert's report is relevant and reliable under Daubert and Rule 702, "the court is not to weigh the evidence relied upon or determine whether it agrees with the conclusions reached therein. . . . Determinations regarding the weight to be accorded, and the sufficiency of, the evidence relied upon by the proffered expert are within the sole province of the jury." [Walker v. Gordon, 46 F. App'x 691, 695 \(3d Cir. 2002\)](#) (*citing* [Breidor v. Sears, Roebuck & Co., 722 F.2d 1134, 1138-39 \(3d Cir. 1983\)](#) ("Where there is a logical basis for an expert's opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge."))).

As to the particulars of causation and diagnosis at issue in this motion, "performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a reliable differential diagnosis," and "their absence makes it much less likely that a differential diagnosis is reliable." [In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 758 \(3d Cir. 1994\)](#). "When a doctor employs standard diagnostic techniques, his or her testimony is much more readily admissible." *Id.*, at 759,

n.27(citing [Hines v. Consolidated Rail Corp., 926 F.2d 262 \(3d Cir. 1991\)](#)). "Part of differential diagnosis is using these standard techniques to rule out alternative causes—thus, where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable." *Id.* An expert is not, however, "required to rule out *all* alternative possible causes." [Heller v. Shaw Industries, Inc., 167 F.3d 146, 156 \(3d Cir. 1999\)](#)(emphasis in original)(citing [Paoli, 35 F.3d, at 759, n.27](#)).

### III. DISCUSSION

Plaintiff indicates that he will not seek case-specific causation testimony from Drs. Adonizio, Bruno, Decker, Falcone, Rybka, and Specter, and withdraws his designation of those doctors as experts on causation. (Doc. [199](#), Ex. 1). Defendant's motion as to those doctors is therefore **DISMISSED** as moot.

#### 1. Dr. Timothy Atkinson

Dr. Atkinson was designated by plaintiff as a non-retained expert witness in this case. Dr. Atkinson is an oral and maxillofacial surgeon licensed to practice in Pennsylvania. He began to treat plaintiff in July of 2005, and was the primary doctor treating his ONJ. Defendant argues that Dr. Atkinson is not an expert on ONJ, and that his deposition testimony reflects that while he was

under the working impression that BPs caused Mr. Bartoli's ONJ, he did not rule out other possible causes of ONJ.

Plaintiff argues that Dr. Atkinson did testify to doing a differential diagnosis. However, this argument lacks merit. Dr. Atkinson did testify that he performed a differential diagnosis as to what the nature of Mr. Bartoli's jaw issue was, determining that it was ONJ. But he did not do a differential diagnosis as to the *cause* of the ONJ. Indeed, he did not even come to a definitive opinion of what caused the ONJ. He specifically stated "no" upon being asked "you didn't in Mr. Bartoli's case determine the underlying cause of the jaw problem?" (Doc. [209](#)-9, at 141). Moreover, when asked whether he had done a differential diagnosis as to determine the cause of the osteonecrosis, Dr. Atkinson responded, "The cause? No." (Id., at 139).

Dr. Atkinson's deposition as a whole does not reflect that he came to any certain conclusions about the cause of Mr. Bartoli's ONJ. Rather it reflects that he was treating Mr. Bartoli's ONJ symptoms and performing procedures to help with the ONJ regardless of the genesis of the problem. Indeed, his lawyer and Mr. Bartoli's lawyer both objected at his deposition on the grounds that he was being asked expert questions and that he was not an expert.

Although Dr. Atkinson did come to a "working impression" that plaintiff was suffering from ONJ caused by BP treatment, plaintiff has failed to evince that Dr. Atkinson arrived at this conclusion through a reliable methodology such as a differential diagnosis. Accordingly, because he lacks a clear opinion

about causation, and moreover because there has been no showing made that even his working impression regarding causation was arrived at through a reliable methodology, Dr. Atkinson may not testify as to specific causation in this case.

## **2. Dr. Arthur Meyer**

Dr. Meyer was also designated as a non-retained expert witness in the case. He is Mr. Bartoli's oncologist who has treated his multiple myeloma since 2000. He prescribed the BP drugs to plaintiff. Defendant argues that Dr. Meyer is not an expert in ONJ, and that he did not perform a differential diagnosis in coming to the conclusion that Mr. Bartoli's ONJ was caused by exposure to the BP drugs.

The court disagrees. While Dr. Meyer does state that he is not an expert in ONJ, that fact is not dispositive. As plaintiff reasonably points out, a doctor cannot be expected to be an "expert" in every disease, adverse medication side effect, or complication that his patients may ever experience. See Holbrook v. Lykes Bros. S.S. Co., Inc., [80 F.3d 777, 783 \(3d Cir. 1996\)](#) (finding that expert need not have "exact background" in order to testify to causation). Dr. Meyer is an expert in oncology, in diagnosing and treating patients with cancer, and that is what he did in this case. That included performing a valid differential diagnosis, which included ruling out alternative causes suggested by defendants. He performed physical examinations and ordered the standard

laboratory tests, classic techniques which compromise performing a differential diagnosis.

Defendant argues, citing Dr. Meyer's deposition, that he failed to rule out "actinomyces (a type of infection), osteomyelitis (another type of infection), herpes zoster (shingles), chemotherapy, steroids, anemia, and osteoporosis." But that is a forced reading of his testimony. He was asked about each of these possible causes, and responded with either a reason for ruling it out, or, for instance, in the case of the shingles, incredulity that he was even being asked because there was no reason to think it has anything to do with ONJ. (Doc. [209](#)-10, at 112-113, 116-117(further explaining how he arrived at his conclusion)). Dr. Meyer is not required to have considered and ruled out any possible cause defendant raises, no matter how unrelated to the ONJ. Rather, he must do what he did here - come to a conclusion by eliminating plausible alternative causes of the ONJ. [See In re Fosamax Products Liability Litig., 2013 WL 1558690 at \\*4 \(D.N.J. Apr. 10, 2013\)](#)(finding that doctor who performed physical examination, reviewed medical history, performed differential diagnosis, and ruled out obvious alternative causes could give specific causation testimony in BP product liability case).

Defendant finally argues that Dr. Meyer did not rule out the presence of multiple myeloma in plaintiff's jaw as the cause of the ONJ, and that he was unsure whether the myeloma or the ONJ appeared in the jawbone first. But he did explain why he considered that ONJ was the cause even while myeloma



was present. (Doc. [209](#)-19, at 85). While the strength of Dr. Meyer's final conclusion is certainly a matter that defendant can attack, he may testify as to specific causation in this case.

### **3. Dr. Robert Marx**

Dr. Marx is a retained litigation-wide expert in the ongoing Aredia<sup>®</sup> and Zometa<sup>®</sup> cases around the country. He is a board-certified oral and maxillofacial surgeon at the University of Miami School of Medicine. He is involved in research concerning bisphosphonates and osteonecrosis of the jaw and was one of first doctors to allege a connection between BPs and ONJ.

Defendant argues that Dr. Marx may not testify as to specific causation in this case because he failed to rule out multiple myeloma as a cause of Mr. Bartoli's ONJ. Defendant also relies heavily on [Perkins v. Novartis Pharm Cirp., 2013 WL 2949045 \(W.D. La. June 14, 2013\)](#), where the court did not allow Dr. Marx to testify as to specific causation because the plaintiff did not have the exposed bone that Dr. Marx stated he believes are necessary for a finding that a patient has BP-caused ONJ. However, the court noted that "there may very well be cases" where Dr. Marx "may have been able to match the actual symptoms and treatment of the patients to his own standards for diagnosing" BP-caused ONJ. *Id.*, at \*4. This is one of the cases, as the reasons for the decision in Perkins are not present.

Here, Dr. Marx reviewed extensive medical and dental records of Mr.

Bartoli. He determined that the exposed bone in Mr. Bartoli's jaw, and its resistance to intense treatment such as antibiotics, hyperbaric oxygen treatment, and surgical debridements,<sup>3</sup> as well as the appearance of the disease on microscopic slides, lead to a conclusion that he has ONJ caused by BP exposure, and not any other disease. (Case No.3:06-cv-0371, M.D. Tenn., Document 31-4). His report as to Mr. Bartoli also notes that he ruled out the conditions that defendant raises as possible alternative causes because he does not believe there is "credible scientific evidence that these treatments or conditions cause" ONJ, and, moreover, that plaintiff does not have these conditions. (Id.). While Dr. Marx admits that Mr. Bartoli's pathology report indicates the return of cancer to plaintiff's jaw, Dr. Marx believes that diagnosis is incorrect. Defendant is free to question the strength of Dr. Marx's opinion and whether he properly ruled out other diseases, including the diagnosis of multiple myeloma in the jaw, but Dr. Marx may testify as to specific causation.

#### **4. Dr. Diane Stern**

Dr. Stern is a retained expert in this litigation. She is an oral pathologist. She has held teaching positions at several medical schools. Unlike Dr. Marx, Dr. Stern's ability to testify as to specific causation has not been widely litigated in these proceedings throughout the country. Defendant objects to her

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<sup>3</sup>Debridement is the removal of unhealthy tissue from a wound to promote healing. <http://www.med.nyu.edu/content?ChunkIID=14803>.

opinion that the diagnosis of cancer in Mr. Bartoli's was incorrect because she did not look at the underlying slides, but only at the pathology report which found that Mr. Bartoli had cancer in his mouth.

Dr. Stern disputes the pathology report because the cancer in the jaw Mr. Bartoli was diagnosed with is "characterized by the proliferation of a single clone of cells," while the report shows that the cells in question are "polyclonal i.e. that these plasma cells did not develop from a single clone." (Case No. 3:06-0371, M.D. Tenn., Document 45-5). Dr. Stern thus believes that the cancer Mr. Bartoli was diagnosed with was not in fact present, and therefore not a possible cause of plaintiff's ONJ. Defendant argues that the cancer in question can appear in a polyclonal form. This dispute is not for the court to decide. Defendants can, of course, ask Dr. Stern about whether she looked at the underlying slides and whether that would have been a better method of reviewing the case, and can question her as to the scientific validity of her opinion regarding the existence of polyclonal multiple myeloma and the literature that indicates that it exists. But defendant's objections all go to the strength of her conclusion, not its admissibility. Dr. Stern may testify as to specific causation.

#### **IV. CONCLUSION**

For the foregoing reasons, defendant's motion to exclude specific causation testimony, (Doc. [159](#)), is **DISMISSED IN PART, GRANTED IN**

**PART, AND DENIED IN PART.** Defendant's motion is **DISMISSED** as moot as to Drs. Adonizio, Bruno, Decker, Falcone, Rybka, and Specter. The motion is **GRANTED** as to Dr. Atkinson. The motion is **DENIED** as to Dr. Meyer, Dr. Marx, and Dr. Stern. A separate order shall issue.

s/ *Malachy E. Mannion*  
**MALACHY E. MANNION**  
United States District Judge

**Date: April 17, 2014**

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